

incorporated into the pharmaceutical compositions.

[0044] Pharmaceutical compositions typically must be sterile and stable under the conditions of manufacture and storage. The composition may be formulated as a solution, microemulsion, liposome, or other ordered structure suitable to high drug concentration. The carrier can be a solvent or dispersion medium containing, for example, water, ethanol, polyol (for example, glycerol, propylene glycol, and liquid polyethylene glycol, and the like), and suitable mixtures thereof. The proper fluidity can be maintained, for example, by the use of a coating such as lecithin, by the maintenance of the required particle size in the case of dispersion and by the use of surfactants. In many cases, it will be preferable to include isotonic agents, for example, sugars, polyalcohols such as mannitol, sorbitol, or sodium chloride in the composition. Prolonged absorption of the injectable compositions can be brought about by including in the composition an agent which delays absorption, for example, monostearate salts and gelatin. Moreover, the pharmaceutical compositions may be administered in a time release formulation, for example, in a composition which includes a slow release polymer. The active compounds can be prepared with carriers that will protect the compound against rapid release, such as controlled release formulation, including implants and microencapsulated delivery systems. Biodegradable, biocompatible polymers can be used, such as ethylene vinyl acetate, polyanhydrides, polyglycolic acid, collagen, polyorthoesters, polylactic acid and polyactic, polyglycolic copolymers (PLG). Many methods for the preparation of such formulations are patented or generally known to those skilled in the art.

[0045] Sterile injectable solutions can be prepared by incorporating an active compound in the required amount in an appropriate solvent with one or a combination of ingredients enumerated above, as required, followed by filtered sterilization. Generally, dispersions are prepared by incorporating the active compound into a sterile vehicle which contains a basic dispersion medium and the required other ingredients from those enumerated above. In the case of sterile powders for the preparation of sterile injectable solutions, the preferred methods of preparation are vacuum drying and freeze-drying which yields a powder of the active ingredient plus any additional desired ingredient from a previously sterile-filtered solution thereof. Pharmaceutical compositions may be formulated with one or more compounds that enhance the solubility of the active compounds.

EXAMPLES

Examples of Preparation Processes:

5 **Example 1: Preparation process of producing PAM-120, PBM=100, and PAN-20**

- 10 [1] Ginseng crude extract 10 g was dissolved in 40 mL of 95% ethanol
- [2] Add 40 mL of 5 N NaOH
- [3] Pour into the reaction tank, and set temperature to 240C, and
- 10 pressure to 3.5 Mpa, for 1.5 hours
- [4] Reduce temperature to room temperature, and take the products out
- the tank
- [5] Add HCl to neutralize pH to about 7, and expend the volume to
- 800 mL using water
- 15 [6] Extract 3 times with acetic ester, 100 mL each time
- [7] Combine all the extracts, and reduce the pressure to dry. Thus,
- obtain 3.8 g of dried extracts
- [8] Grind and dissolved the extract in 20 mL of methanol, and mix the
- methanol solution with silica gel
- 20 [9] Dry up the mixture, and then grind to fine powder
- [10] Load the Silica gel column
- [11] Wash the column with 60 mL of ether:petroleum benzin (1:3), and
- thus, 250 mg of PAM-120, and 45 mg of PBM-100 were obtained
- 25 [12] Wash the column with 90 mL of chlorofom:methanol (95:5), and
- thus 50 mg of PAN-20 was obtained. -

Example 2: Another example of preparation process producing PAM-120, PBM-100, and PAN-20

- 30 [1] 10 g of Ginseng crude extract was added into reaction tank
- [2] Add to the reaction tank 100 mL of 5 N NaOH
- [3] Set temperature to 270C and pressure to 4.5 Mpa for 1 hour
- [4] Reduce temperature to room temperature, then take out the
- products
- [5] Neutralize the pH to 7 using HCl
- 35 [6] Filter and keep the solids
- [7] Dissolve the solids in 10 mL of 95% Ethanol
- [8] Add water to make ethanol content less than 5%

- [9] Sit still overnight
[10] Filter and keep the solids
[11] Dry the solids
[12] Dissolved the solids in 10 mL of methanol
[13] Filter and keep the solution
[14] Dry the solution to obtain 3.6 g of products
[15] Mix the products with 11 g of silica gel
[16] Grind and then load the silica gel column
[17] Wash the column with 100 mL of ether:petroleum benzin (1:3),
and thus, 60 mg of PAM-120, and 65 mg of PBM-100 were
obtained
[18] Wash the column with chloroform:methanol (95:5), and thus 60
mg of PAN-20 was obtained.

Example 3: Comparison of Cancer Cell Inhibition Effects *In Vitro* Between Ginsenoside 20(S)-Rh2 and Novel Dammarane Sapogenins PAM-120, PBM-100, PAN-30 and their Composition

A. Method

[0046] Composition: 20(S)-Rh2 was provided by Shenyang Pegasus

Pharmaceutical R&D Co., China, with a purity of over 98%. The molecular weight for Rh2 was 622.3. Sapogenins PAM-120, PBM-100 and PAN-30 were derived from the process stated in Example 1. The molecular weights of PAM-120, PBM-100 and PAN-30 were respectively 442.7, 474.7 and 604.9, and the purity for each of the three agents was higher than 99%. Rh2, PAM-120, PBM-100 and PAN-30 were dissolved 1 gram each separately in 100 mL absolute ethanol and stored at 4°C. the agents were diluted with RPMI-1640 medium to the desired concentrations as shown in Table 1.

[0047] Cells: Human non-small-cell lung carcinoma H460 cells were incubated in RPMI-1640 medium added with 10% fetal calf serum, 100 units penicillin/ml, and 100µg streptomycin/ml in 5% CO₂ at 37°C.

[0048] In vitro treatment: H460 cells were seeded in 96-well flat-bottomed microtest-plates at 1.2x10³ cells per well, six wells in each group, incubated in humidified 5% CO₂ at 37°C for 24 hours with or without the agents according to the schedule as shown below.